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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/025,947

12/26/2001

Hsuan-Yin Lan-Hargest

12938-003002

8464

27890 7590 04/09/2010  
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EXAMINER

ZUCKER, PAUL A

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

04/09/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/025,947	<b>Applicant(s)</b> LAN-HARGEST ET AL.	
	<b>Examiner</b> Paul A. Zucker	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Current Status**

1. This action is responsive to Applicants' amendment of 19 January 2010.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 are pending.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 102 are finally rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support for the limitation excluding the subgenii defined in lines 23 -32 and 22-30, respectively :

"that when L contains three double bonds, said hydrocarbon chain is further substituted with C<sub>2-4</sub> alkenyl, C<sub>2-4</sub> alkynyl, C<sub>1-4</sub> alkoxy, hydroxyl, halo, amino, nitro, C<sub>3-5</sub> cycloalkyl, 3-5 membered heterocycloalkyl, monocyclic aryl, 5-6 membered heteroaryl, C<sub>1-4</sub> alkylcarbonyloxy, C<sub>1-4</sub> alkylcarbonyl, or formyl; and further provided that when L is C<sub>4</sub> or C<sub>5</sub> ~~C<sub>3-7</sub>~~ and contains one triple bond or ~~one or~~ two double bonds and A is phenyl or substituted phenyl, Y<sup>1</sup> is not a bond or -CH<sub>2</sub>-<sub>1</sub> and Y<sup>2</sup> is -CH<sub>2</sub>-; provided that when L is C<sub>4</sub>, A is C<sub>3-14</sub> cycloalkyl then Y<sub>1</sub> is not CH<sub>2</sub>; and further provided that when L is C<sub>4</sub> containing two double bonds, and is ω-substituted with phenyl or substituted phenyl, A is not phenyl or substituted phenyl;"

The claim language constitutes new matter because the written description of the instant specification does not “reasonably lead” those skilled in the art to this particular subgenus of compounds. (MPEP 2163.05).

***Examiner’s Response to Applicants’ Remarks With Regard to This Rejection***

5. Applicants have neither argued against this rejection nor amended the claims in a manner that obviates it.

Applicant's arguments filed 19 January 2010 have been fully considered but they are not persuasive for the reasons set forth above.

6. Claim 22 is finally rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support for the limitation excluding the subgenii defined in lines 16 -19 :

“that when L contains three double bonds, said hydrocarbon chain is further substituted with C<sub>2-4</sub> alkenyl, C<sub>2-4</sub> alkynyl, C<sub>1-4</sub> alkoxy, or amino; and further provided that when L is C<sub>4</sub> or C<sub>5</sub> C<sub>3-7</sub> and contains one triple bond or ~~one or~~ two double bonds and A is phenyl or substituted phenyl, Y<sup>1</sup> is not a bond or -CH<sub>2</sub>-<sub>1</sub> and Y<sup>2</sup> is -CH<sub>2</sub>-;” .

The claim language constitutes new matter because the written description of the instant specification does not “reasonably lead” those skilled in the art to this particular subgenus of compounds. (MPEP 2163.05).

***Examiner’s Response to Applicants’ Remarks With Regard to This Rejection***

7. Applicants have neither argued against this rejection nor amended the claims in a manner that obviates it.

Applicant's arguments filed 19 January 2010 have been fully considered but they are not persuasive for the reasons set forth above.

8. Claims 80, 91 and 103 are finally rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support for the limitation excluding the subgenii defined in lines 23 -27, 21-25 and 18-22, respectively :

provided that when L is C<sub>4</sub>, A is C<sub>3-14</sub> cycloalkyl then Y<sub>1</sub> is not CH<sub>2</sub>; and further provided that when L is C<sub>4</sub> containing two double bonds, and is ω-substituted with phenyl or substituted phenyl, A is not phenyl or substituted phenyl; further provided that when L is C<sub>4</sub> or C<sub>5</sub> C<sub>3-7</sub> and contains one triple bond or ~~one or~~ two double bonds and A is phenyl or substituted phenyl, Y<sup>1</sup> is not a bond or -CH<sub>2</sub>-<sub>1</sub> and Y<sup>2</sup> is -CH<sub>2</sub>-,"

The claim language constitutes new matter because the written description of the instant specification does not "reasonably lead" those skilled in the art to this particular subgenus of compounds. (MPEP 2163.05).

***Examiner's Response to Applicants' Remarks With Regard to This Rejection***

9. Applicants have neither argued against this rejection nor amended the claims in a manner that obviates it.

Applicant's arguments filed 19 January 2010 have been fully considered but they are not persuasive for the reasons set forth above.

10. The rejections under 35 USC § 102, set forth in paragraphs 11-13 of the previous Office Action mailed 19 October 2009 are withdrawn in response to Applicant's amendment.

11. The objection to the claims, set forth in paragraph 14 of the previous Office Action mailed 19 October 2009 is withdrawn in response to Applicant's amendment.

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***New Rejections***

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-5, 7, 8, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 are finally rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 22, 80, 91, 102 and 103 recite the limitation "contains one triple bond" in lines 26-27, 18, 26, 25, 26 and 21, respectively. There is insufficient antecedent basis for this limitation in the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1621

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4, 12, 13, 22, 102 and 103 and are rejected under 35 U.S.C. 102(b) as

being anticipated by Fujisawa et al (Chemistry Letters, Regioselectivity of  $\beta$ -Vinyl- $\beta$  - Propiolactone Toward Various Nucleophiles, 1982, (1), pages 71-74, abstract).

Fujisawa discloses (See search listing last page), the compound Ph-S

$\text{CH}_2\text{CH}=\text{CHCH}_2\text{CO}_2\text{H}$ . Ph-S  $\text{CH}_2\text{CH}=\text{CHCH}_2\text{CO}_2\text{H}$  corresponds to an instantly

claimed compounds in which A is phenyl (unsubstituted), L is a  $\text{C}_3$  trans olefin

containing a triple bond,  $\text{Y}^1 = \text{S}$ ,  $\text{Y}^2 = \text{CH}_2$ ,  $\text{X}_1, \text{X}_2 = \text{O}$ . Fujisawa therefore anticipates

claims 1-4, 12, 13, 22, 102 and 103.

14. Claims 1-5, 12, 13, 22, 80-84, 87, 88 and 102 are rejected under 35 U.S.C. 102(b)

as being anticipated by Lopez et al (International Journal of Pharmaceutics, Skin

Permeation Model of Phenylalkylcarboxylic Homologous Acids and Their Enhancer Effect on Percutaneous Penetration of 5-Fluorouracil, 1996, 139, pages 205-217).

Lopez discloses (Page 208, column 1, bottom, Table 1) a series of phenyl alkanoic

acids corresponds to an instantly claimed compounds in which A is phenyl

(unsubstituted), L is a  $\text{C}_{3-7}$  saturated chain,  $\text{Y}^1 = \text{a bond}$ ,  $\text{Y}^2 = \text{CH}_2$ ,  $\text{X}_1, \text{X}_2 = \text{O}$ . Lopez

discloses (Page 211, column 2, top, Fig 4) pharmaceutical compositions of these

compounds.. Lopez therefore anticipates claims 1-5, 12, 13, 22, 80-84, 87, 88 and

102.

***Conclusion***

15. Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 are pending.

Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-84, 87-94, 96, 97 and 99-103 are finally rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/  
Primary Examiner, Art Unit 1621